EXHIBIT 2

Article Link: http://www.webmd.com/urinary-incontinence-oab/news/20140519/removal-of-faulty-mesh-for-incontinence-may-not-improve-womens-symptoms

Incontinence & Overactive Bladder Health Center

Listen

Removal of Faulty Mesh for Incontinence

Experts say there's still no clear-cut answer as to whether or not to have surgery

WebMD News from HealthDay

By Amy Norton

HealthDay Reporter

MONDAY, May 19, 2014 (HealthDay News) -- Removal of vaginal mesh -- a device implanted to help support a woman's pelvic organs -- won't necessarily improve side effects such as pain and incontinence related to the device, suggests the mixed results from a pair of new studies.

The findings, reported Monday at the American Urological Association's annual meeting, come at a time of growing safety concerns over vaginal mesh devices. Last month, the U.S. Food and Drug Administration (FDA) said it will require stricter oversight of the products -- specifically, as they are used to treat pelvic organ prolapse. The FDA now classifies these devices as "high-risk."

In pelvic organ prolapse, the structures supporting the bladder, uterus and rectum weaken and stretch. The organs may drop from their normal position and protrude into the vagina, which can cause pelvic pain, discomfort during sex, and problems with urination and defecation.

Some women with pelvic organ prolapse eventually need surgery to reposition and secure the pelvic organs. In the 1990s, doctors started using vaginal mesh implants to give extra support to the organs after surgery.

But over time, the FDA began receiving reports of problems linked to the devices. There were cases where the mesh eroded, and women suffered infections, bleeding or pain; some women developed new or worsening urinary problems or pain during sex.

It's not always clear, though, that a woman's symptoms are caused by the device, or that surgically removing it will help.

"In the worst-case scenario, you have a recurrence of the [pelvic organ prolapse symptoms] and the patient still has the pain" attributed to the device, said Dr. Philippe Zimmern, a urologist at the University of Texas Southwestern Medical Center in Dallas, who worked on one of the new studies.

That study followed 123 women who had surgery to remove either a mesh device or another synthetic device called suburethral tape.

And the news from this study was good. Most of the women -- including 67 percent of those with the mesh device -- became pain-free after surgery. And on average, patients' pain ratings were much lower two to three years after surgery versus before the surgery.

continued...

A big caveat, however, is that pain had been the sole issue for all of the women before surgery.

The second study, by researchers at the University of California, Los Angeles, had less-positive results. It surveyed 214 women about three years after they'd had their mesh implants removed; these patients had opted for surgery due to a range of symptoms, not only pain.

Post-surgery, many women continued to have problems, the study found. Although two-thirds of the women said they had no pain or only mild symptoms, the rest had moderate to severe pain. Twenty-eight percent said they had urine leakage at least once a day, and half had pain during sex, according to the study.

The study, however, had its own limits. The researchers sent surveys to nearly 700 women who'd had surgery at their center, but only one-third responded. It's possible that women who'd continued to have problems were more likely to respond.

So what should women do? Zimmern said that despite the good results in his study, women should not rush into surgery.

"We can only say that in this subset of patients, the outcomes were better than we expected," Zimmern said.

It can't be assumed that the results would extend to women more generally. For one, Zimmern explained, pain was the only reason for device removal, and it's not clear that the outcomes would be the same for women who had pain and other symptoms.

Plus, Zimmern said, the study included no patients who'd gone with nonsurgical options -- like physical therapy for the pelvic floor muscles, or "trigger point" injections with medications that ease pain and inflammation.

"This study might have included a select group of women," Zimmern said.

The issue is complicated, agreed Dr. Tomas Griebling, a professor of urology at the University of Kansas Medical Center in Kansas City.

"I think most [doctors] would advise patients with no adverse signs or symptoms that they do not need to undergo surgical removal of mesh implants," said Griebling, who was scheduled to moderate a discussion of the studies at the meeting.

continued...

But when it comes to women who are having symptoms, the decision about what to do is not clear-cut.

Zimmern suggested that the safest course is to try nonsurgical options first. When women do opt for surgery, they need to realize that some symptoms might improve while others might get worse, Griebling said.

If you had incontinence before the mesh was implanted, then developed pain because of mesh erosion, removing it might ease your pain. "But you might experience worse incontinence," Griebling said.

He and Zimmern both suggested that women read the FDA recommendations on the devices, available on the agency's website.

The implants are still in use, and the recent FDA action applies only to vaginal mesh used for pelvic organ prolapse -- and not the other uses for mesh implants. They are often used to treat stress incontinence and as part of abdominal surgery for pelvic organ prolapse, for example.

Because these studies were presented at a meeting, findings should be viewed as preliminary until they've been published in a peer-reviewed journal.

Top Picks

Tame MS-Related Bladder Issues

Symptoms of Incontinence

Urine Color and Odor: What They Really Mean

Foods That Make You Gotta Go

Herbal Remedies for OAB

Types of Incontinence

SOURCES: Philippe Zimmern, M.D., professor, urology, University of Texas Southwestern Medical Center, Dallas; Tomas Griebling, M.D., M.P.H., professor, urology, University of Kansas Medical Center, Kansas City; May 19, 2014, presentation, American Urological Association annual scientific sessions, Orlando, Fla.

HealthDay

Copyright © 2013-2014 HealthDay. All rights reserved.

My Notes: